

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

**EP 0 478 155 B1**

(12)

**EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:  
**28.01.1998 Bulletin 1998/05**

(51) Int. Cl.<sup>6</sup>: **A61M 25/00**

(21) Application number: **91308016.4**

(22) Date of filing: **02.09.1991**

(54) **Delivery catheter**

Injektionskatheter

Cathéter d'injection

(84) Designated Contracting States:  
**BE DE FR GB IT**

(30) Priority: **28.09.1990 US 589794**

(43) Date of publication of application:  
**01.04.1992 Bulletin 1992/14**

(73) Proprietor: **OVAMED CORPORATION**  
**Palo Alto, California 94301 (US)**

(72) Inventor: **Schatz, Richard A.**  
**Rancho Santa Fe, California 92067 (US)**

(74) Representative: **Coxon, Philip**  
**Eric Potter & Clarkson**  
**St. Mary's Court**  
**St. Mary's Gate**  
**Nottingham NG1 1LE (GB)**

(56) References cited:  
**EP-A- 0 381 062** **FR-A- 2 635 453**  
**US-A- 4 033 331**

• **PATENT ABSTRACTS OF JAPAN vol. 13, no. 336**  
**(C-623)(3684) 27 July 1989 & JP-A-1 113 073**  
**(OLYMPUS OPTICAL CO LTD ) 1 May 1989**

**BEST AVAILABLE COPY**

**EP 0 478 155 B1**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

## Description

### FIELD OF THE INVENTION

The present invention generally pertains to devices for introducing matter into a body cavity. More specifically, the present invention pertains to delivery catheters which can be guided through body passageways to deposit living matter at a desired location in the passageway. The present invention is particularly, but not exclusively, useful for depositing fertilized eggs or gametes in the fallopian tubes of a female mammal to initiate gestation.

### BACKGROUND OF THE INVENTION

It is well-known that infertility is a subject which has been of great interest and concern within the medical community. This is so, in part, because it is known that infertility may result for several reasons. For example, the male and female gametes may have different antibodies which prevent fertilization. Further, it may happen that the male has a low sperm count or that the female gamete is not capable of being fertilized. There may also be mechanical factors involved. For instance, if the fallopian tubes of the female have been impaired by a disorder or have been somehow blocked, such as by a tubal ligation, it will be necessary to deposit a fertilized egg directly into the uterus, rather than the fallopian tube, before there can be any possibility of gestation.

Numerous procedures have been suggested to accomplish the intrafallopian transfer of zygotes or gametes. One of the more widely used and well-known medical procedures is laparoscopy. For laparoscopy, the fertilized egg is implanted in the distal third portion of the fallopian tube via a surgical procedure which requires an incision in the abdominal wall of the female. A syringe-like device is then inserted through the incision to deposit a fertilized egg at the desired site within the fallopian tube. Laparoscopy, however, is a surgical operation with potential complications. For example, if the required surgical incision is not properly closed, the healing process may be unnecessarily prolonged. Moreover, as with any surgical procedure requiring operative incisions, a mandatory recuperation period in the hospital is required. Also, as with other surgical procedures requiring operative incisions, there is relatively a greater risk of infection than with medical procedures that do not require operative incisions.

It is known, however, that access into body passageways need not necessarily require surgical operative incisions and, instead, may be accomplished using catheters. Indeed, catheter technology has developed markedly in several areas of medical technology. Specifically, catheters are frequently used in cardiology. As an example, for transluminal coronary angioplasty, catheters are inserted into the cardiovascular system in

order to remodel a blockage or obstruction in the artery. Indeed, such a catheter is disclosed and claimed in U.S. Patent No. 4,571,240 to Samson et al. for an invention entitled "Catheter Having Encapsulated Tip Marker". In accordance with the Samson et al. disclosure, a catheter is inserted into the coronary artery over a prepositioned guide wire until an inflatable balloon is positioned across the lesion to be compromised. In another application, U.S. Patent No. 3,968,800, which issued to Vilasi for an invention entitled "Device for Insertion into a Body Opening" discloses a catheter-like device which is an essentially hollow tube which is useful as endotracheal tubes, bronchoscopes, vascular and cervical dilators and the like. Although these and other devices are exemplary of catheters and their varied uses, none of these devices are intended to deal with the problems associated with infertility. Further, they do not suggest the use of a catheter for depositing living matter into a body passageway for subsequent gestation. Importantly, the present invention recognizes a catheter can be used for delivering zygotes into the fallopian tubes of a female mammal without requiring operative incisions.

In light of the above, it is an object of the present invention to provide a catheter for introducing living matter into a body passageway. Another object of the present invention is to provide a delivery catheter that can accomplish intrafallopian transfer of zygotes on an outpatient basis. Still another object of the present invention is to provide a catheter which can accomplish intrafallopian transfer of zygotes through direct access of the catheter to the fallopian tube through a body orifice. Yet another object of the present invention is to provide a delivery catheter that is relatively easy to operate, relatively simple to manufacture and comparatively cost-effective for its intended purposes.

### SUMMARY OF THE INVENTION

A delivery catheter is provided to initiate gestation by introducing living matter, such as zygotes or gametes, into the fallopian tubes of a female mammal. In accordance with the present invention, there is provided a delivery catheter for depositing living matter at a desired location in a body cavity or passageway, which comprises: a collection chamber for holding said living matter, said chamber having a single ejection port formed in the side wall of the collection chamber adjacent to the distal end of the collection chamber, the ejection port thus being positionable at said desired location, and wherein the ejector port is sufficiently large to allow the living matter to be safely ejected from the delivery catheter, said collection chamber further having an actuator port; and a syringe engageable with said actuator port for introducing fluid into said collection chamber to eject said living matter from said chamber through said ejection port into said passageway; guide means associated with said collection chamber for positioning said ejection port in said body cavity or

passageway, wherein said guide means comprises: a guide wire, prepositionable into said body cavity or passageway; and a tube attached to said collection chamber, said tube having a lumen for slidably receiving said guide wire therethrough to advance said chamber along said guide wire.

Patent Abstracts of Japan, Vol. 13, no. 336 (C-623) (3684) 27 July 1989 discloses a catheter comprising an outer tube with a large diameter portion and an inner tube with an expanded part to hold the material to be implanted and a fine diameter part with an open end to release the material.

FR 2635453 discloses a catheter comprising an introductory catheter with an inclined tip, a mandrel used to straighten this inclined tip during insertion and a fine diameter catheter having a drawn-down tip which is inserted through the introductory catheter after the mandrel has been removed.

EP 381062 discloses a catheter which is designed for delivery of therapeutic fluids such as thrombolytic fluids to a patient's blood vessel and the outer tube of the catheter has a plurality of flow passageways with openings of increasing diametrical dimensions, so that a desired flow of treatment fluid can be delivered exteriorly of the catheter body.

In operation of the catheter of the invention, the guide wire is initially positioned through a body orifice and into the desired body passageway; for example, through the vagina and cervix, and into the fallopian tube. Before insertion of the delivery catheter into the body passageway, the delivery catheter is primed by filling the collection chamber with fluid. Zygotes are then collected in the collection chamber and held therein near the ejection port. For insertion of the delivery catheter into the body passageway, the prepositioned guide wire is slidably received into the lumen of the guide tube and the guide tube and its associated collection chamber are then advanced along the guide wire. Once the ejection port of the collection chamber is positioned at the desired site in the body passageway, ejection of the living matter (ie the zygotes), from the collection chamber is accomplished by introducing fluid into the collection chamber through the actuator port.

The novel feature of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic showing the present invention operatively positioned through a body passageway;

Figure 2 is a perspective view of the preferred embodiment of the delivery catheter according to the present invention;

Figure 3 is a cross-sectional view of the catheter as seen along the line 3-3 in Figure 2;

Figure 4 is a cross-sectional view of the catheter as seen along the line 4-4 in Figure 2;

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring initially to Figure 1, a delivery catheter according to the present invention is generally designated 10 and is shown operatively positioned in a female reproductive system 12.

The portions of the female reproductive system 12 shown in Figure 1 include the ovaries 14 in which ova 16 are produced, the fallopian tubes 18 in which fertilization is normally accomplished, and the cervix 28 through which sperm must pass en route to their destiny with the ova in the fallopian tube 18. Under normal conditions of fertilization, ova 16 are conveyed from the ovary 14 to the distal third portion 20 of fallopian tube 18 by ciliated motion via the fimbria 22 and fimbria ovarica 24.

As shown in Figure 1, delivery catheter 10 is positioned through the os externum 26 of cervix 28 through the uterus 30 and through the os 32 into the fallopian tube 18. When properly positioned, the distal end 34 of delivery catheter 10 is located in the distal third portion 20 of fallopian tube 18. Figure 1 also shows a syringe 36 engaged with actuator port 38.

Referring now to Figure 2, it will be seen that the delivery catheter 10 comprises an elongated, flexible guide tube 40 which is formed with a lumen 42. As shown, guide tube 40 is concentrically positioned inside a tubular-shaped collection chamber 44 which is disposed as a sheath 46 in a surrounding relationship to guide tube 40. Further, it can be seen in Figure 2 that collection chamber 44 is formed with an ejection port 48 near its distal end 50 and with an actuator port 38 near its proximal end 52. As perhaps better appreciated with reference to Figure 3, the proximal end 52 and distal end 50 of the collection chamber 44 are joined in respective fluid-tight seals 54 with the proximal end 58 and distal end 56 of guide tube 40. For purposes of the present invention, the fluid-tight seals 54, are made in any manner well-known in the pertinent art such as by gluing or solvent bonding.

As will be seen in cross-reference between Figures 2 and 3, the ejection port 48 is formed in the wall 60 of collection chamber 44 adjacent to its distal end 50. Preferably, ejection port 48 is sufficiently large enough to allow living matter to be safely ejected from delivery catheter 10. Preferably, ejection port 48 is circular and has a diameter 59 of approximately one half millimeter (0.5 mm). The actuator port 38 is also formed in the wall 60 of collection chamber 44 and, although shown in Figures 2 and 3 as being located adjacent or near the proximal end 52 of the collection chamber 44, the actuator port 38 can be formed anywhere along wall 60 of collection chamber 44 in accordance with the desires of the

operator. In any event, actuator port 38 has a fitting 64 which extends from the wall 60 of collection chamber 44 for engagement with a syringe 36 or other fluid-injecting device.

Figures 2, 3 and 4 also show that guide wire 66 is slidably received through the lumen 42 of guide tube 40. For purposes of the present invention, guide wire 66 may be any steerable or positionable guide wire that is well-known in the pertinent art. Importantly, guide wire 66 must be capable of being properly positioned in the body passageway and is biologically compatible with the body.

## OPERATION

In its operation, the delivery catheter 10 of the preferred embodiment is first primed with a biologically compatible fluid, such as a saline solution, and a syringe 36 is operatively engaged to the actuator port 38 of collection chamber 44. The ejection port 48 of collection chamber 44 is then placed in a container (not shown) which holds the zygotes 94 that are to be introduced into the fallopian tube 18, and the zygotes 94 are drawn into collection chamber 44 through ejection port 48 by proper operation of the syringe 36. It will be appreciated that delivery catheter 10 can also be primed with gametes instead of zygotes.

The guide wire 66 is initially inserted through a body orifice, such as the vagina of a female mammal, and is disposed with its distal end 76 positioned in the distal third portion 20 of fallopian tube 18. The guide tube 40 of delivery catheter 10 is engaged with the guide wire 66 to slidably receive guide wire 66 into the lumen 42 of the guide tube 40, and delivery catheter 10 is then advanced into position along guide wire 66. With the ejection port 48 of collection chamber 44 positioned in the distal third portion 20 of fallopian tube 18, ejection of zygotes 94 from collection chamber 44 is accomplished by introducing fluid into the collection chamber 44 through the actuator port 38. In accordance with the present invention, this introduction of fluid is accomplished by use of a syringe 36 or other fluid-injecting device.

## Claims

1. A delivery catheter for depositing living matter at a desired location in a body cavity or passageway, which comprises:

a collection chamber (44) for holding said living matter, said chamber having an actuator port (38); the catheter further comprising a syringe (36) engageable with said actuator port for introducing fluid into said collection chamber to eject said living matter from said chamber through said ejection port into said passageway;

guide means (42,66) associated with said collection chamber (44) for positioning said ejection port (48) in said body cavity or passageway, wherein said guide means comprises:

a guide wire (66), prepositionable into said body cavity or passageway;

characterised by

the chamber (44) having a single ejection port (48) formed in the side wall (60) of the collection chamber (44) adjacent to the distal end (50) of the collection chamber (44), the ejection port (48) thus being positionable at said desired location, and wherein the ejector port (48) is sufficiently large to allow the living matter to be safely ejected from the delivery catheter (10),

and whereby the guide means further comprises

a tube (40) attached to said collection chamber, said tube having a lumen (42) for slidably receiving said guide wire therethrough to advance said chamber along said guide wire.

2. A delivery catheter as recited in claim 1 wherein said collection chamber (44) is formed as a sheath (46) surrounding said tube (40).
3. A delivery catheter as recited in claim 1 or 2 wherein said tube (40) and said collection chamber (44) are made of a flexible material.
4. A delivery catheter according to any one of the preceding claims, wherein the ejection port (48) is substantially circular and has a diameter (59) of 0.5 mm.
5. A delivery catheter according to any one of the preceding claims, wherein the living matter is a gamete or a zygote and the desired location is the distal third portion of a fallopian tube.

## Patentansprüche

1. Injektionskatheter zum Deponieren lebender Materie an einer gewünschten Stelle in einer Körperhöhle oder in einem Durchgang, umfassend

eine Sammelkammer (44) zur Aufnahme der lebenden Materie, wobei die Kammer eine Betätigungsöffnung (38) aufweist und der Katheter des weiteren eine mit der Betätigungsöffnung zusammenfügbare Spritze (36) zum Einführen von Fluid in die Sammelkammer umfaßt, um die lebende Materie aus der Kammer durch die Ausstoßöffnung in den Durchgang auszustoßen, sowie mit der Sammelkammer (44) zusammenwir-

kende Führungsmittel (42, 66) zum Positionieren der Ausstoßöffnung (48) in der Körperhöhle oder in dem Durchgang, wobei die Führungsmittel einen in der Körperhöhle oder dem Durchgang vorpositionierbaren Führungsdraht (66) umfassen, dadurch gekennzeichnet,

daß die Kammer (44) eine einzelne Ausstoßöffnung (48) aufweist, die in der Seitenwand (60) der Sammelkammer (44) nächst dem distalen Ende (50) der Sammelkammer (44) ausgebildet ist, so daß die Ausstoßöffnung (48) an der gewünschten Stelle positionierbar ist, wobei die Ausstoßöffnung (48) genügend groß ist, um ein sicheres Ausstoßen der lebenden Materie aus dem Injektionskatheter zu gestatten, und daß die Führungsmittel des weiteren ein an der Sammelkammer befestigtes Rohr (40) mit einer lichten Weite (42) zur gleitenden Aufnahme dem Führungsdrahts durch diese aufweisen, um die Kammer längs des Führungsdrahts vorwärtszubewegen.

2. Injektionskatheter gemäß Anspruch 1, wobei die Sammelkammer (44) als eine das Rohr (40) umgebende Hülle (46) ausgebildet ist.
3. Injektionskatheter gemäß Anspruch 1 oder 2, wobei das Rohr (40) und die Sammelkammer (44) aus flexiblem Material hergestellt sind.
4. Injektionskatheter gemäß einem der vorangehenden Ansprüche, wobei die Ausstoßöffnung (48) im wesentlichen kreisförmig ist und einen Durchmesser (59) von 0,5 mm hat.
5. Injektionskatheter nach einem der vorangehenden Ansprüche, wobei die lebende Materie eine Gamete oder eine Zygote, und die gewünschte Stelle der dritte distale Abschnitt einer Eileiterröhre ist.

#### Revendications

1. Cathéter d'injection pour déposer une matière vivante à un endroit souhaité d'une cavité ou d'un chemin corporels, qui comprend :

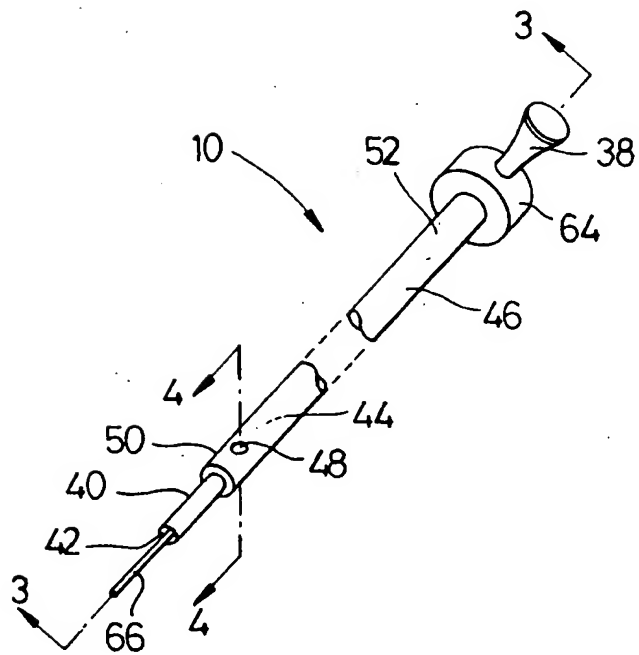
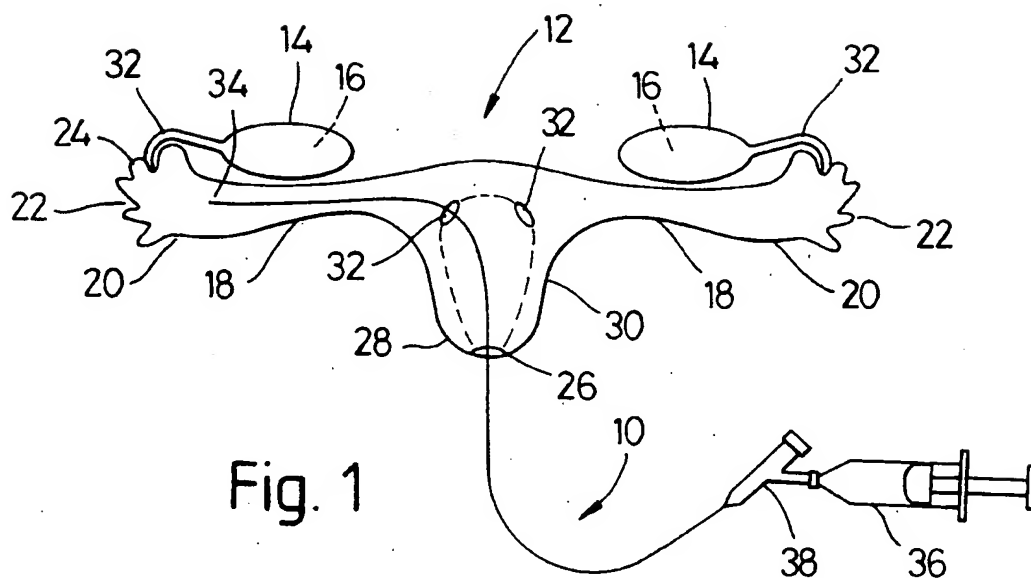
une chambre collectrice (44) pour conserver ladite matière vivante, ladite chambre ayant un orifice d'actionnement (38) ; le cathéter comprenant en outre une seringue (36) pouvant venir en prise avec ledit orifice d'actionnement pour introduire du fluide dans ladite chambre collectrice afin d'éjecter ladite matière vivante hors de ladite chambre à travers ledit orifice d'éjection dans ledit passage ; des moyens de guidage (42, 66) associés à

ladite chambre collectrice (44) afin de positionner ledit orifice d'éjection (48) dans ladite cavité ou ledit passage corporels, dans lesquels lesdits moyens de guidage comprennent :

un fil de guidage (66), positionnable à l'avance dans ladite cavité ou ledit passage corporels, caractérisé en ce que la chambre (44) a un seul orifice d'éjection (48) formé dans la paroi latérale (60) de la chambre collectrice (44) adjacente à l'extrémité distale (50) de la chambre collectrice (44), l'orifice d'éjection (48) pouvant être ainsi positionnée audit emplacement souhaité, et dans lequel l'orifice d'éjection (48) est suffisamment grand pour permettre à la matière vivante d'être éjectée en toute sécurité du cathéter d'injection (10), et les moyens de guidage comprenant en outre :

un tube (40) fixé à ladite chambre collectrice, ledit tube ayant une lumière (42) pour recevoir de manière coulissante ledit fil de guidage à travers celui-ci afin de faire avancer ladite chambre le long dudit fil de guidage.

2. Cathéter d'injection selon la revendication 1, dans lequel ladite chambre collectrice (44) est formée d'une gaine (46) entourant ledit tube (40).
3. Cathéter d'injection selon la revendication 1 ou 2, dans lequel ledit tube (40) et ladite chambre collectrice (44) sont fabriqués en matériau souple.
4. Cathéter d'injection selon l'une quelconque des revendications précédentes, dans lequel l'orifice d'éjection (48) est sensiblement circulaire et possède un diamètre (59) de 0,5 mm.
5. Cathéter d'injection selon l'une quelconque des revendications précédentes, dans lequel la matière vivante est un gamète ou un zygote et l'emplacement souhaité est le tiers distal d'une trompe de Fallope.



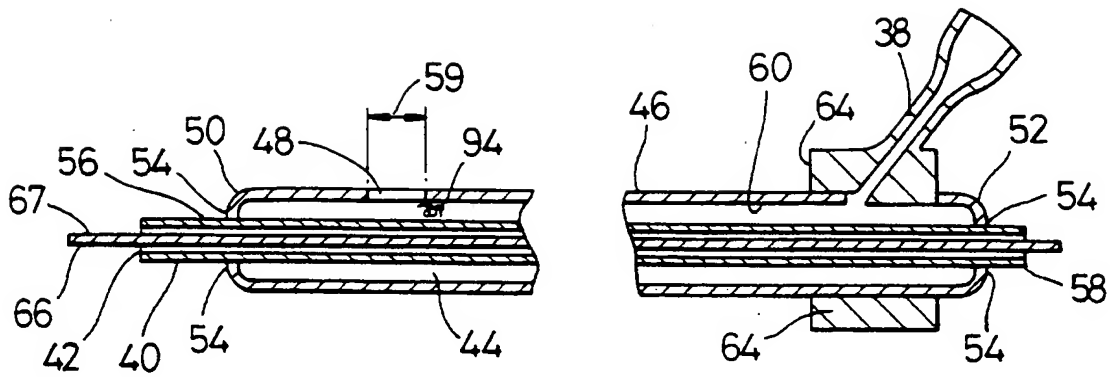


Fig. 3

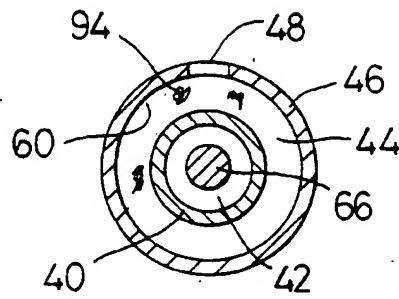


Fig. 4

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**